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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

September 30, 2004

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 2004-DAL-WL-33

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Carl E. King, President
WNCK, Inc.
2408 Timberloch Place, Suite A-4
The Woodlands, Texas 77380

Dear Mr. King:

Our review of information collected during an inspection of your firm's manufacturing operations located at the above-referenced address on June 10 through 18, 2004, revealed that your firm manufactures the BreathScan® Detector, a device that is intended for the screening of alcohol impairment by individuals engaged in work or driving. This product is a device as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, you were issued a Form FDA-483 which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization [21 CFR 820.20]. For example, your firm (a) has not appointed a management representative nor provided the necessary quality system training to this employee; (b) has not established procedures for management reviews nor conducted such reviews; and (c) has not established quality system procedures and instructions, including, but not limited to, procedures for internal quality audits, purchasing controls, complaint handling, acceptance or rejection of in-coming and finished products, device master records, and corrective and preventive action plans. See FDA-483 Items 1 through 7 issued to and discussed with you.

2. Failure to establish and maintain procedures for quality audits and the conduct of such audits [21 CFR 820.22]. See FDA-483 Item 2.

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198(a)] [FDA-483 Item 5]. For example, your firm (a) has not established written complaint handling procedures to indicate how complaints are investigated, documented, and handled; and (b) has not maintained complaint files.

4. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50] [FDA-483 Item 3]. For example, your firm has not (a) maintained purchasing documentation that clearly references the quality requirements that must be met by the contract manufacturer and supplier, including an agreement with them to notify your firm of changes in the product or service and (b) established procedures describing your firm's quality assessments of the contract manufacturer and supplier.

5. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure [21 CFR 820.70(b)]. Your firm has not established procedures describing how your firm or your firm's contract manufacturer initiates, describes, approves, and verifies or validates changes made to device specifications and manufacturing processes. For example, you reported that your contract manufacturer made a change in the device in order to pass the U.S. Department of Transportation's requirements for an evidentiary tester at the 0.02% breath alcohol concentration level, and there is no documentation showing the procedures followed by the manufacturer to initiate, describe, approve, and verify or validate this change.

6. Failure to establish and maintain procedures for acceptance or rejection of incoming and finished product to ensure that each production run, lot, or batch of incoming and finished devices meets acceptance criteria [21 CFR 820.80(b) and (d)] [FDA-483 Item 4]. For example, your firm has not (a) documented the inspection/testing results of your firm's acceptance or rejection of the incoming and finished product; and (b) established procedures describing your quality inspection methods and acceptance/rejection criteria.

7. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100(a)] [FDA-483 Item 7]. For example, your firm maintained electronic communication records with distributors or customers, but there were no records showing your firm's evaluation of or action taken on quality issues.

8. Failure to maintain device master records that include or refer to the location of packaging and labeling procedures and specifications [21 CFR 820.181] [FDA-483 Item 6]. For example, your firm has not established procedures for your labeling and packaging activities, including documenting all the labels and labeling used for device packaging in the device history records.

The Act requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country. Because you do not have marketing clearance from FDA, marketing your BreathScan® Detector is in violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device, your device is adulterated under the Act because you do not have an approved premarket approval application that shows your device is safe and effective. Your BreathScan® Detector is also misbranded under the Act because you did not submit a section 510(k) premarket notification which shows that your device is substantially equivalent to other devices that are legally marketed.

Our inspection also documented that you have not registered your facility as a medical device manufacturer and listed the devices with the FDA to ensure compliance with Section 510 of the Act and 21 CFR 807. Failure to register a firm's facilities and list its devices with FDA constitutes misbranding under section 502(o) of the Act. You can obtain the registration and listing form from our website at http://www.fda.gov.

We acknowledge receiving your letter, dated July 16, 2004, responding to the inspectional observations listed on the Form FDA-483 issued to you at the close of our inspection on June 18, 2004. You responded that you promised to correct the GMP observations and specified a timeframe of 60 to 90 days for completing your corrective action. Your response is incomplete for the following reasons: (a) you have not indicated your willingness to submit a 510(k) premarket notification for FDA's review and clearance; (b) you have not provided status update reports explaining what specific GMP corrections have been completed and specific GMP procedures have been established; and (c) you have not provided training records showing you and your employees have attended and completed the quality system training.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective action and preventative action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Should you need general information about FDA's requirements for medical device manufacturers, you may obtain information on the FDA's website at http://www.fda.gov or by contacting our Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at (800) 638-2041.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address. If you have any questions concerning this matter, you may contact Mr. Ta at (214) 253-5217.

Sincerely,

Michael A. Chappell
Dallas District Director

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